REMARKS

Claims 1-6 and 8-15 are pending in this application. Claims 1-6 and 8-15 were rejected under 35 U.S.C. §112, first paragraph. Claims 1-6 and 8-10 were rejected under 35 U.S.C. §112, second paragraph. Claims 1-4, 6, 9 and 10 were rejected under 35 U.S.C. §102(e). Claims 5, 8, 11-15 were variously rejected under 35 U.S.C. §103.

By this amendment, claims 1 and 11 have been amended without prejudice or disclaimer of any previously claimed subject matter. Support for the amendments can be found, *inter alia*, throughout the specification including, for example, at page 32, lines 8-10.

The amendments are made solely to promote prosecution without prejudice or disclaimer of any previously claimed subject matter. With respect to all amendments and cancelled claims, Applicant has not dedicated or abandoned any unclaimed subject matter and moreover has not acquiesced to any rejections and/or objections made by the Patent Office. Applicant expressly reserves the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Applicant has carefully considered the points raised in the Office Action and believe that the Examiner's concerns have been addressed as described herein, thereby placing this case into condition for allowance.

Information Disclosure Statement

Applicant thanks the Examiner for entry of the information disclosure statement on January 27, 2003. Applicant notes, however, that the Form PTO-1449 accompanying the Office Action is uninitialed. Applicant respectfully requests that the Examiner initial and return the initialed Form PTO-1449, indicating that the information has been considered and made of record herein.

Rejections under 35 U.S.C. §112, first paragraph

Claims 1-6 and 8-15 were rejected under 35 U.S.C. §112, first paragraph, for allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant respectfully traverses this rejection.

The Examiner appears to base the rejection on the assertion that "one of skill in the art would have had to perform undue experimentation in order to use the invention as claimed." In support, the Examiner states that "the specification teaches a method of the invention which is shown not to function as claimed" and that "working examples in the specification cannot be overlooked in favor of the results reported in the declaration of Dr. Van Nest because the results of Dr. Van Nest do not appear to have been available at the time the invention was filed." Office Action, page 4.

Applicant respectfully disagrees with this assertion and this interpretation of the teachings of the specification.

Applicant respectfully submits that experimental results provided in the specification support suppression of RSV infection by demonstrating RSV titer reduction in response to administration of an ISS-containing polynucleotide at the site of RSV exposure. Contrary to the assessment by the Examiner, the results presented in Table 2 of the specification show an approximately 20-fold reduction in viral titer upon administration of an ISS-containing polynucleotide. As noted in the specification and by the Examiner, the results in Table 2 are "not quite statistically significant." However, this certainly does not mean that the experimental results demonstrate that the invention does not work nor does this mean that the method does not work as claimed. The data demonstrate that ISS administration results in a reduced RSV titer, thus suppression of an RSV infection.

Dr. Van Nest's declaration (submitted January 14, 2003) provides results of an experiment performed as described in Examples 1 and 2 of the specification. In this experiment, model animals treated with a 150 microgram dose of an ISS-containing polynucleotide showed a statistically significant reduction in RSV lung titer of greater than 100-fold compared to that of animals treated with phosphate buffered saline control.

Both experiments were performed in the same way and the data from both show a reduction in RSV titer. Contrary to the Examiner's statement, Applicant never asked that the experimental result in the specification be overlooked in favor of that presented in the declaration. Rather, the declaration was provided to demonstrate that an additional experiment performed in the same manner again results a reduction in RSV titer, including a statistically significant reduction. Both the experimental data presented in the specification and in the declaration support the claimed invention and demonstrate that the invention functions as claimed.

Thus, Applicant respectfully submits that no undue experimentation would be required for one skilled in the art to make and use the claimed invention. Applicant thus respectfully submits that the pending claims fall within the subject matter that is enabled by the specification.

Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, first paragraph.

Rejections under 35 U.S.C. §112, second paragraph

Claims 1-6 and 8-10 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant respectfully traverses this rejection.

Although Applicant believes that the claims were sufficiently definite when considered in view of the specification and the understanding of those of skill in the art, Applicant has

attempted to respond to the concerns of the Examiner in order to enhance clarity and to facilitate disposition of the present case.

In view of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, second paragraph.

Rejections under 35 U.S.C. §102(e)

Claims 1-4, 6, 9 and 10 were rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Krieg et al., U.S. Pat. No. 6,218,371 ("Krieg"). Applicant respectfully traverses this rejection.

The claimed invention is directed to a method of suppressing a respiratory syncytial virus (RSV) infection in an individual who has been exposed to RSV through administration of a composition comprising an ISS-containing polynucleotide to the respiratory tract of the individual in an amount sufficient to suppress an RSV infection. As amended herein, in the claimed method, neither an RSV antigen nor an immunostimulatory cytokine is administered in conjunction with administration of the composition.

On the contrary, Krieg "relates to synergistic combinations of immunostimulatory CpG oligonucleotides and immunopotentiating cytokines." Krieg, column 1, lines 12-14. Throughout the disclosure, Krieg describes "methods and products for inducing a synergistic immune response using a combination of a CpG oligonucleotide and a cytokine." Krieg, column 3, lines 6-8.

For a claim to be anticipated by a reference, the reference much teach each and every element of the claim. As noted above, the claimed invention excludes administration of an immunostimulating cytokine in conjunction with the ISS-containing polynucleotide. Krieg does not teach the claimed invention.

Thus, Applicant respectfully submits that Krieg does not anticipate the claimed invention.

Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. §102(e).

Rejections under 35 U.S.C. §103

Claims 11-14 were rejected under 35 U.S.C. § 103 as allegedly being unpatentable over Krieg et al., U.S. Pat. No. 6,218,371 ("Krieg"). Claims 5, 8 and 15 were rejected under 35 U.S.C. § 103 as allegedly being unpatentable over Krieg and further in view of Raz et al., U.S. Pat. No. 6,498,148 ("Raz"). Applicant respectfully traverses these rejections.

In addition to the claimed method described above, the claimed invention is also directed to a kit for use in the method comprising a composition comprising an ISS-containing polynucleotide and instruction for administration of the composition to the respiratory tract of an individual. The claimed kit does not contain an RSV antigen or an immunostimulatory cytokine.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20USPQ2d 1438 (Fed. Cir. 1991); MPEP §2143.

As noted above, Krieg describes administration of synergistic combinations of immunostimulatory CpG oligonucleotides and immunopotentiating cytokines. Thus, Krieg provides no teaching or suggestion of the claimed invention. Further, Applicant respectfully submits that there is no suggestion or motivation in Krieg to modify the teachings therein to arrive at the claimed invention.

As noted by the Examiner, Raz teaches the immunostimulatory oligonucleotide of SEQ ID NO:1 of the present invention. Although Raz teaches a particular immunostimulatory sequence, the combination of Krieg and Raz does not teach or suggest all the limitations of the claimed invention. Further, Applicant respectfully submits that there is no suggestion or motivation in Krieg and/or Raz to modify the teachings therein to arrive at the claimed invention.

Thus, Applicant respectfully submits that a *prima facie* case of obviousness has not been established.

Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. §103.

CONCLUSION

Applicant believes that all issues raised in the Office Action have been properly addressed in this response. Accordingly, reconsideration and allowance of the pending claims is respectfully requested. If the Examiner feels that a telephone interview would serve to facilitate resolution of any outstanding issues, the Examiner is encouraged to contact Applicant's representative at the telephone number below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 377882000900.

Dated: June 18, 2003

Respectfully submitted,

By Karen R. Zachow

Karen R. Zachow
Registration No.: 46,332
MORRISON & FOERSTER LLP
3811 Valley Centre, Suite 500
San Diego, California 92130
Telephone: (858) 720-5191
Facsimile: (858) 720-5125